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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,543	01/15/2004	Gary L. Griffiths	40923-0132US1	3062

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,543	GRIFFITHS, GARY L.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-80* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-32 and 47-55, as specifically drawn to a conjugate of an anthracycline drug and an antibody, classified in class 530, subclass 391.9.

II. Claims 33-44, 56-57 and 59-72, as specifically drawn to a method for treating a disease in a mammal comprising administering a conjugate of an antibody and an anthracycline drug, classified in class 424, subclass 181.1.

III. Claims 45, 46 in part, 58 and 73-79, as specifically drawn to a method for treating a disease in a mammal comprising administering two or more conjugates of an antibody and an anthracycline drug that target different epitopes of the same antigen on the same diseased cells, classified in class 424, subclass 181.1.

IV. Claims 46, 58 and 73-78, as specifically drawn to a method for treating a disease in a mammal comprising administering a conjugate of an antibody and an anthracycline drug preceded by, concomitantly with, or subsequent to a second antibody-based treatment, such that the second antibody in the second antibody-based treatment targets a different antigen on disease cells than the antibody in the conjugate, classified in class 424, subclass 181.1.

V. Claim 80, as specifically drawn to a conjugate of an anthracycline drug and an antibody, wherein said anthracycline drug and said antibody are linked via a linker comprising a hydrazide and a maleimide and wherein an immunomodulator is further conjugated to said antibody, classified in class 530, subclass 391.9.

The inventions are distinct, each from the other because of the following reasons:

The conjugates of Group I and Group V are related by the virtue that both have similar activities. However, the structure of the products are different. For example, the conjugate of Group I comprises an anthracycline conjugated to an antibody, wherein the antibody only needs to have one reactive group for the conjugation to occur. In contrast, the conjugate of Group VI comprises an anthracycline which is conjugated to an antibody, wherein the antibody is further conjugated to an immunomodulator. Thus, the antibody of Group VI would require two sites for binding. Moreover, the conjugates may be made by materially differently methods, which would require distinct steps and materials. Therefore, the inventions are patentably distinct.

The inventions of Groups II-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The method for treating a disease in a mammal comprising administering a conjugate of an antibody and an anthracycline drug (Group II), method for treating a disease in a mammal comprising administering two or more conjugates of an antibody and an anthracycline drug that target different epitopes of the same antigen on the same diseased cells (Groups III) and the method for treating a disease in a mammal comprising administering a conjugate of an antibody and an anthracycline drug preceded by, concomitantly with, or subsequent to a second antibody-based treatment, such that the second antibody in the second antibody-based treatment targets a different antigen on disease cells than the antibody in the conjugate (Group IV) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for treatment differ significantly for each of the materials. For treatment, either a single conjugate comprising an anthracycline linked to an antibody or two or more conjugates comprising an anthracycline linked to an antibody, wherein the each antibody binds to a different epitope of the same antigen or two completely different conjugates comprising an anthracycline linked to an antibody, wherein the antibody binds to two distinctly different antigens may be used. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups II-IV are patentably distinct.

The inventions of Group I and Groups II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the conjugate as presently claimed can be used in a materially different process of using that product wherein the conjugate can either be used alone or in combination with a second conjugate, wherein the second conjugate may comprise an antibody portion that recognizes the same antigen but different epitope or may recognize a different patentably distinct antigen.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

Claim 6, Group I, is generic to a plurality of disclosed patentably distinct species comprising the following cancers: carcinomas, sarcomas, lymphomas, leukemias, gliomas, or skin cancers which differ at least in etiology and pathology.

Claims 8, 9, 10, 19, 20 , Group I, are generic to a plurality of disclosed patentably distinct species comprising the following tumor-associated antigens: CD74, Cd22, EPG-1, ...myeloid cells and antigens associated with hematologic malignancies each of which differ in etiology and amino acid sequence.

Claims 11, 52, Group I, are generic to a plurality of disclosed patentably distinct species comprising the following antibodies: LL1, LL2, L243, ... RS11 and 17-1A each of which differ at least in amino acid sequence and specificity.

Claims 13, 32, Group I, are generic to a plurality of disclosed patentably distinct species comprising the following anthracycline drugs: daunorubicin, dozorubicin, epirubicin, 2-pyrrolinodoxorubicin, morpholino-doxorubicin, and cyanomorpholino-doxorubicin each of which differ in chemical structure.

Claims 39, 40 and 41, Group II, are generic to a plurality of disclosed patentably distinct species comprising the following cancers: skin cancer, head-and-neck cancer, breast cancer, prostate cancer, ... sarcoma, melanoma, B-cell or T-cell cancer which differ at least in etiology and pathology.

Claims 59, 66, 73, Group II, III, IV, are generic to a plurality of disclosed patentably distinct species comprising the following immunomodulators: interferons, cytokines, stem cell growth factors, colony-stimulating factors, lymphotoxins and other hematopoietic factors which differ at least in etiology and pathology.

-If Applicants choose hematopoietic factors from claims 59, 66 and 73 than claims 61, 63, 68, 70, 75 and 77 are generic to a plurality of patentably distinct species comprising the following hamatopoietic factors: interleukins, colony stimulating factors, granulocyte macrophage-colony stimulating factor, erythropoietin, thrombopoietin, G-CFS and GM-CFS.

-If Applicants choose interleukins from claims 61, 68, 75 than claims 62, 69, 76 are generic to a plurality of patentably distinct species comprising the following interleukins: IL-1, IL-2, IL-3, ... IL-18 and IL-21.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds

one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
11/14/05